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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,991	03/15/2006	Laurent Francois Andre Hennequin	056291-5242	5523

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EXAMINER	
WILLIS, DOUGLAS M	

ART UNIT	PAPER NUMBER
4161	

MAIL DATE	DELIVERY MODE
04/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,991	HENNEQUIN ET AL.	
	Examiner	Art Unit	
	DOUGLAS M. WILLIS	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims / Priority

1. Claims 1-37 are pending in the current application. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/GB2004/003937 filed September 15, 2004, which claims priority under 35 U.S.C. § 119(e) to EP 03292309.6 filed September 19, 2003 and EP 04291248.5 filed May 14, 2004.

Restrictions

2. Restriction is required under 35 U.S.C. § 121 and § 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

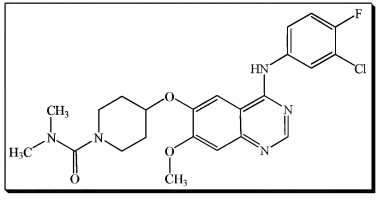
> Group I, claims 1-31 and 33, is drawn to a quinazoline derivative of the formula I and a pharmaceutical composition thereof.
>
> Group II, claim 32, is drawn to a process for preparing a quinazoline derivative... which comprises either processes a-m.
>
> Group III, claims 34-36, is drawn to a method for producing an anti-proliferative effect in a warm-blooded animal… which comprises administering… a quinazoline derivative of the formula I... and uses as a medicament and in the manufacture of a medicament.
>
> Group IV, claim 37, is drawn to a compound of the formula VI, VII, VIII, X or XX, as defined in claim 32, or a salt thereof.

3. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions." Moreover, as stated in

PCT Rule 13.2, the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled "where a group of inventions is claimed in one and the same international application only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features."

The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art, so linked, as to form a single general inventive concept." The quinazoline derivatives of the Formula I, recited in claim 1, lack novelty under PCT Article 33(2) as being anticipated by WO 03/082290; thus, the quinazoline derivatives of the Formula I, do not present a contribution over the prior art. Furthermore, as currently presented, the quinazoline derivatives of the Formula I do not share special technical features with the process and other compounds used for their preparation, recited in claims 32 and 37, or methods of their use, recited in claims 34-36. Consequently, the technical relationship and required "unity" among Groups I-IV, is disrupted.

4. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a) prior art recited in claim 1 of WO 03/082290, provided in the file,



anticipates one of the currently claimed quinazoline derivatives of the Formula I. One species encompassed by this claim, 4-[(3-chloro-4-fluorophenyl)amino]-6-{1-[(dimethylamino)carbonyl]-piperidin-4-yl-oxy}-7-methoxy-quinazoline, is indicated above.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

A. A quinazoline derivative of the formula I wherein R^1-R^{12}, n, m and X^1 is...

[claims 1-31]

Examiner requests applicant elect a single species clearly identifying R^1-R^{12}, n, m and X^1, where applicable.

B. A process for preparing a quinazoline derivative... which comprises either processes *a-m*. [claim 32]

Examiner requests applicant elect a single species clearly identifying which process selected from *a-m*, will be used for the preparation of a quinazoline derivative and any other species contained within selected process (i.e. $R^{1-*\circ}$, Lg, T, protecting group, etc.).

C. A pharmaceutical composition which comprises a quinazoline derivative… in association with a pharmaceutically acceptable diluent or carrier. [claim 33]

Examiner requests applicant elect a single species clearly identifying the pharmaceutically acceptable diluent or carrier.

D. A method for producing an anti-proliferative effect in a warm-blooded animal… which comprises administering… a quinazoline derivative of the formula I... [claim 36]

Examiner requests applicant elect a single species clearly identifying which anti-proliferative effect is targeted by the recited method.

E. A compound of the formula VI, VII, VIII, X or XX, as defined in claim 32, or a salt thereof wherein R^1, R^2, R^3, R^{3a}, R^5, n, m, Lg, T and X^1 is… [claim 37]

Examiner requests applicant elect a single species clearly identifying R^1, R^2, R^3, R^{3a}, R^5, n, m, Lg, T and X^1, where applicable.

The claims are deemed to correspond to the species listed above in the following manner: Group I - claims 2-31 and 33; Group II - claim 32; Group III - claims 34-35; and Group IV - claim 37.

The following claim(s) are generic: Group I - claims 1 and 33; Group II - claim 32; Group III - claim 36; and Group IV - claim 37.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each chemical species is a distinct chemical which lacks a special technical feature in view of the prior art. WO 03/082290 teaches the use of

compounds, such as 4-[(3-chloro-4-fluorophenyl)amino]-6-{1-[(dimethylamino)carbonyl]-piperidin-4-yl-oxy}-7-methoxy-quinazoline, in the treatment of cancer diseases and inhibition of tyrosine kinase-mediated signal transduction.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. § 101 and/or 35 U.S.C. § 112, first paragraph.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Applicant is required, in reply to this action, to elect a single species, ***for searching purposes and prosecution on the merits only***, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on

the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include: **(i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143)** and **(ii) identification of the claims encompassing the elected invention.**

A telephone call was made to Ms. Michele Bosch on April 8, 2008 to request an oral election to the above species requirement, but, after 48 hours, did not result in an election.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Friday from 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Patrick Nolan, can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. M. W./
Examiner, Art Unit 4161

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161